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Martin J. Jacobs

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03/17/2009

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/975,350	<b>Applicant(s)</b> JACOBS ET AL.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8-13,15-43,45-50,55-60 and 63-66 is/are pending in the application.
- 4a) Of the above claim(s) 36-43,56-58,60,64 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8-13,15-35,45-50,55,59,63 and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/3/09</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Examiner acknowledges receipt of IDS filed 02/03/09, terminal disclaimer, amendment and remarks filed 11/25/08. No claim is currently amended. Claims 1, 3, 4, 8-13, 15-43, 45-50, 55-60 and 63-66 are pending. Claims 36-43, 56, 57, 58, 60, 64 and 65 were withdrawn from consideration and are withdrawn from consideration.

### ***Response to Arguments***

Previous rejections that are not reiterated herein are withdrawn, for example, the filing of terminal disclaimer overcomes the obviousness-type double patenting rejection over US 6,489,363.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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3. Claims 1, 3, 4, 8-13, 15, 17-35, 45-47, 55, 59, 63 and 66 are rejected under 35 U.S.C.

103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Esteve et al. (US 6,566,404 B2 as English translation for WO 99/25329) or in view of applicant's admitted prior art for reasons of record and reiterated herein below.

4. Nguyen teaches a pharmaceutical composition comprising particles or microparticles of active ingredient, physiologically acceptable hydrophilic excipient and water (abstract). The hydrophilic excipient comprises a polymer component and a water-soluble or water dispersible component that acts as a diluent (column 6, lines 1-5). The polymer component is selected from the group consisting of gum Arabic, xanthan gum, gum tragacanth, alginates, pectinates, polyvinylpyrrolidone, polyethylene glycols, cellulose, carboxymethyl cellulose, cellulose ethers, carboxymethyl chitin, dextran, chitosan, gelatin, acrylic and methacrylic polymers and copolymers, colloidal silica and mixtures thereof (column 6, lines 11-23). The polyethylene glycol meets claim 15. The water-soluble or water dispersible component is selected from the group consisting of lactose, glycerol, mannitol, glucose, sucrose, maltodextrin, cyclodextrins and derivatives thereof (column 6, lines 44-49). The hydrophilic excipients can also comprise surfactants that are capable of oral administration and the surfactants can be polysorbates, sorbitan esters, fatty glyceride polyethers, lecithins, sodium lauryl sulfate, sodium dioctylsulfosuccinate and mixtures thereof (column 7, lines 2-7) meeting surfactant requirements of claims 8-13, 19, 21-31. The process of preparing the modafinil particles involves homogenization of the active ingredient in solution, suspension, or emulsion and freeze-drying or lyophilization (column 8, lines 15-24) and the modafinil meets claims 1, 3, 17, 18-20, 32-35, 45, 55, 63, 66. The active ingredient is selected from the group consisting of paracetamol, probucol,

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piroxicam, phloroglucinol, tiadenol, flerobuterol, modafinil, dexfenfluramine, carbinoxamine maleate, loperamide, lorazepam and mixtures thereof (claim 13). Claims 45-47 recite the properties of the composition; and oral administration is route of administration and route of administration of a composition is does not patentably distinguish the claimed composition over the prior art since the composition of Nguyen, a modafinil composition is capable of being orally administered; specifically lyophilized product of Nguyen contains surfactants capable of oral administration (column 7, lines 3-7). Thus, Nguyen specifically envisions oral administration and since the excipients listed are pharmaceutically acceptable, it flows that the modafinil composition of Nguyen is pharmaceutically acceptable and claim 4 is met.

The preparation is lyophilized such that the amount of water is driven to a minimum and would be less than 10% meeting the non-aqueous nature of claim 1 (as gleaned from applicant's specification at paragraph [0020] of the published specification describing non-aqueous composition). Regarding the amounts of surfactant in claims 8, 9, 23-25, 27-30; and regarding the amount of modafinil in claims 17 and 18, it is within the purview of the artisan to use amounts of surfactants and modafinil in the composition to provide the desired composition. However, Nguyen is silent on the optical character of the modafinil. But it is known in the art that modafinil in the absence of designation of d- or l-, is the racemic form comprises of the l- or d- form. In the absence of factual evidence, the use of the specific l-form of the modafinil is not inventive over the use of the racemic form.

Nguyen does not teach a liquid composition. However, it is known to formulate modafinil as liquid solutions according to applicant's admitted prior art (instant specification at paragraphs [0006] and [0007] of the published application and Esteve (see column 2, line 58;

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column 3, lines 9-16). Furthermore, Nguyen teaches using organic solvent such as polyethylene glycol as described above. Therefore, since liquid modafinil formulations are known in the art as noted above, and taking the teachings of the references together and all the critical elements being taught, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that the lyophilized product of Nguyen can be successfully reconstituted as a liquid formulation.

### ***Response to Arguments***

5. Applicant's arguments filed 11/25/08 have been fully considered but they are not persuasive.

6. Nguyen in view of Esteve:

7. Applicant argues that the combination of Nguyen and Esteve does not teach all the elements of the claims because neither Nguyen nor Esteve address the limitation that the "non-aqueous liquid solution comprising a modafinil compound ... characterized in that the solution spontaneously forms [a] homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium. The examiner agrees with the applicant that neither Nguyen nor Esteve describes the composition as having the characteristic of forming stable composition of non-crystalline particles when the solution contacts aqueous medium. The examiner also notes that in determining obviousness, a combination of references need not result precisely in applicant's structure, rather, the question is whether the invention would have been obvious in light of the combination. In the present case, the invention would have been obvious in light of the combination because, since modafinil composition has been known to be formulated in liquid form, the person of ordinary skill in the art at the time the invention was made

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would have reasonable expectation of success that the modafinil in the formulation of Nguyen in liquid form when administered would be bio-available in the subject.

8. Applicant further argues that the Nguyen requires the use of mechanical assistance to form homogenous mixtures. While it may be the case that Nguyen requires mechanical assistance to make homogenous mixture, it is noted that the examined claims are directed to compositions and not to how the composition is prepared such that Nguyen does not have to teach the exact method steps of how the composition is made while noting the rejection is under 35 USC 103.

9. Applicant argues that Nguyen's lack of discussions that the composition form aqueous, liquid homogenous stable composition when placed in contact with aqueous medium "forecloses" the examiner's arguments for inherency and that the burden is on the Office to establish what particular property is inherent. Applicant has further cited MPEP 2112.IV that rejections cannot be based on data or information not actually present in the cited prior art. The examiner disagrees with applicant that a composition such as the claimed composition cannot intrinsically have the properties of forming aqueous, ... stable compositions when contacted with an aqueous medium because the formation of aqueous, .. stable composition when place in contact with aqueous medium is a characteristic/property of the composition and applicant acknowledges this also in at least last paragraph of page 2 of 8 of the remarks filed 11/25/08. Applicant had the burden of establishing or factually showing that the composition of Nguyen does not have the property of forming aqueous, ... stable compositions when contacted with an aqueous medium and "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are

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not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). With regards to MPEP 2112 [R-3] IV, it is clear that the PTO does not have laboratories to test and validate what applicant would want the PTO to do and MPEP 2112 [R-3] IV discusses that results that may occur based on optimization or invitation to further experimentation is not sufficient to establish inherency. None of the situations examined in MPEP 2112 [R-3] IV is applicable here because, it is the composition that undergoes or exhibits the recited characteristic. In the same way the composition of Nguyen in liquid form has would have the capacity of exhibiting or undergoing that change when placed in contact with aqueous medium. That property or characteristic is intrinsic to the composition as claimed and as disclosed.

10. Applicant further argues that Esteve does not cure Nguyen’s deficiency since Esteve just like Nguyen does not teach that the modafinil containing composition would form aqueous, ... stable compositions when contacted with an aqueous medium. The examiner agrees with the applicant that neither Nguyen nor Esteve describes the composition as having the characteristic of forming stable composition of non-crystalline particles when the solution contacts aqueous medium. But, the forming of aqueous, ... stable compositions when contacted with an aqueous medium is a characteristic or property of the composition and neither of the references need teach that in order for the composition to intrinsically exhibit that property; further, Esteve was not combined with Nguyen to provide an intrinsic property that is innate to the composition.

11. In all applicant has argued the references individually when a combination of references was used in the rejections. And, it is noted that, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re*



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*Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The current rejections are based upon *Nguyen* in view of *Esteve*.

12. Claims 1, 3, 4, 8-13, 15, 17-35, 45-47, 55, 59, 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Nguyen et al.* (US 5,843,347) in view of *Shah et al.* ("Self-emulsifying drug delivery systems (SEDDS) with polyglycolized glycerides for improving in vitro dissolution and oral absorption of lipophilic drugs," in *international Journal of Pharmaceutics*, 106 (1994), pp 15-23) or *Charman et al.* ("Self-emulsifying Drug Delivery Systems: Formulation and Pharmaceutical Evaluation of an Investigational Lipophilic Compound," in *Pharmaceutical Research*, Vol. 9, No. 1, 1992, pp 87-93) for reasons of record and reiterated herein below.

13. *Nguyen* has been described above as rendering obvious the designated claims except that, *Nguyen* failed to specifically teach liquid formulation containing modafinil. Modafinil is a lipophilic drug or is a drug that is insoluble in water as evidenced by column 1, lines 32-35 of US 6,348,500 B1). However, *Charman* and *Shah* individually each disclose the formulation of poorly water soluble drugs using self-emulsifying drug delivery systems (see the whole publications, with emphasis on Table 2 and page 18, left column of the *Shah* reference and page 88 of *Charman*). Therefore, taking the general teachings of the references, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that adapting the teachings of *Shah* or *Charman* in formulating the modafinil composition of *Nguyen* would produce a self emulsifying formulation of modafinil in liquid form that after oral administration would readily disperse in the stomach to form fine emulsion.

***Response to Arguments***

14. Applicant's arguments filed 11/25/08 have been fully considered but they are not persuasive.

15. Applicant's arguments here are the same as that for Nguyen in view of Esteve or Grebow in that the combination of Nguyen and Shah or Nguyen and Charman does not disclose every element of claim 1 since Nguyen fails to teach that the composition when in contact with aqueous medium would form aqueous, ... stable compositions. The examiner disagrees in the same way as was noted above. The formation of aqueous, ... stable compositions when the composition is placed in contact with an aqueous medium is the characteristic of the composition and the composition of Nguyen in view of Esteve or Grebow or Shah or Charman would be capable of showing that intrinsic characteristic.

16. Applicant's arguments that the claimed compositions are distinct over Shah and Charman is noted. But the rejection is made over Nguyen in view of Shah or Charman, which means that the primary reference is Nguyen. Furthermore, the examiner agrees that the claimed composition is distinct over Shah or Charman as the arguments relate to the claimed composition and that is why, the claims are rejected under 35 USC 103 with the rejections finding that the claims are not patentable over the combination of Nguyen and Shah or Nguyen and Charman. Poor solubility of modafinil in lipids and water is a characteristic of modafinil and the prior art need not teach that. Shah and Charman both teach the formulation of lipophilic drugs as oil solutions (see page 18 at the third full paragraph under "Formulation for SEEDS" for Shah and pages 87 and 88 for Charman) so that modafinil, a lipophilic drug would be expected to be successfully prepared as a solution in oil. Therefore, the rejection is maintained.

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17. Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Shah et al. ("Self-emulsifying drug delivery systems (SEDDS) with polyglycolized glycerides for improving in vitro dissolution and oral absorption of lipophilic drugs," in international Journal of Pharmaceutics, 106 (1994), pp 15-23) for reasons of record and reiterated herein below.

Nguyen in view of Shah is described above as rendering obvious the liquid formulation of claims 1 and 47. Nguyen teaches all the critical elements of the claims except that the formulation of Nguyen is not an encapsulated liquid. But Shah teaches soft gelatin capsules containing liquid compositions of lipophilic drugs (see the entire publication with emphasis on page 18 and Table 2). Therefore, one having ordinary skill in the art at the invention was made would have reasonable expectation of success that adapting the teachings of Shah in formulating the modafinil composition of Nguyen, liquid compositions of modafinil encapsulated in soft gelatin capsules would produce a self emulsifying formulation of modafinil in liquid form in gelatin capsules that after oral administration would readily disperse in the stomach to form fine emulsion.

***NOTE: Applicant has not argued against the above rejections of claims 48-50.***

18. Claims 1, 3, 4, 8-13, 15, 17-35, 45-50, 55, 59, 63 and 66 rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Grebow et al. (US 5,618,845) for reasons of record and reiterated herein below.

19. Nguyen has been described above. Nguyen teaches all the critical elements of the claims. Nguyen does not specifically teach a liquid formulation.

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Grebow teaches a pharmaceutical composition comprising modafinil particles or modafinil pharmaceutically acceptable salt particles (abstract, column 2, column 3, lines 1-55 and claims 1 and 2) and non-toxic pharmaceutically acceptable carrier (column 4, lines 4-1%). Grebow's composition contains an appropriate dosage of between 50 mg and 700 mg of modafinil with a preferred amount of 400 mg (column 4, lines 11-18 and column 10, lines 15-17). The modafinil pharmaceutical composition is administered as a tablet, capsule, powder, pill, liquid, suspension or emulsion; the modafinil composition can also be administered topically via epidermal patch or administered via direct injection (column 10, lines 18-26). Grebow further teaches a method of altering somnolent state, for example, narcolepsy, idiopathic hypersomnia and related sleep disorders by administering to a mammal a pharmaceutical composition comprising an effective amount of modafinil particles; and an effective amount of the pharmaceutical composition is defined as an amount effective for treating the somnolent state (column 3, lines 56-67). In human clinical trials, modafinil is administered to physically and mentally healthy male subjects (column 5, lines 46 to 56). Regarding claim 67, Grebow teaches liquid or suspension or emulsion composition of modafinil.

The composition of Grebow encompasses stable and unstable suspensions because the prior art does not exclude stable suspensions and thus the suspension of Grebow would be inherently stable. It is also noted that Grebow discloses suspensions containing modafinil and in the suspension modafinil is not crystalline and the particles of modafinil are suspended in the solvent. The composition of Grebow can also be administered as a liquid as described above which meets the limitation of claim 1 requiring a liquid composition. Regarding claims 48-50,

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the modafinil composition of Grebow is encapsulated and would therefore meet claim 48 with the generic teaching of capsule encompasses hard and soft capsules of claims 49 and 50.

Grebow also teaches administering the prior art composition in clinical trials to mentally and physically healthy male subjects. Orally administering modafinil particles to human subjects (column 5, lines 46-56) would necessarily bring modafinil particles in contact with the aqueous environment in the human subject since human body is mostly water. the prior art is silent on the form of the capsule. Since the prior art is silent on the form of the capsule, hard or soft gelatin capsule, the prior art broad teaching of a capsule encompasses both soft gelatin capsule or hard capsule. The expected result would be the encapsulation of modafinil particle in soft or hard gelatin capsule meeting claims 48-50. Therefore, regarding soft or hard capsule, one of ordinary skill in the art is capable of encapsulating the composition in hard or soft in hard capsule or soft gelatin capsule.

Nguyen teaches all the critical elements of the claims. Nguyen does not specifically teach a liquid formulation. Grebow teaches liquid formulation of modafinil. Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that the teaching of Grebow can be adapted to successfully prepare liquid formulation of modafinil as anticipated by Grebow. One having ordinary skilled artisan would have reasonable expectation of success to encapsulate the product of Nguyen for oral administration.

### ***Response to Arguments***

20. Applicant's arguments filed 11/25/2008 have been fully considered but they are not persuasive.

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21. Applicant argues that the combination of Nguyen and Grebow does not address every element of applicant's claims because Nguyen does not teach or suggest a composition that forms aqueous, ... stable compositions when contacted with an aqueous medium and that Grebow, which also fails to teach a composition that forms aqueous, ... stable compositions when contacted with an aqueous medium does not cure the deficiency. The examiner disagrees because the formation of aqueous, ... stable compositions when contacted with an aqueous medium is a characteristic property and Grebow was not used to cure that which is intrinsic to a particular product/composition.

Claim 1 is a non-aqueous composition comprising modafinil compound and at least one surfactant with the composition having the characteristic that it would form an aqueous, liquid, homogeneous, stable composition of non-crystalline particles when contacted with an aqueous medium. The composition of Nguyen is a non aqueous solution comprising modafinil and surfactant and would inherently have the characteristic that when it is contacted with aqueous medium it would inherently form aqueous, liquid, homogeneous, stable composition of non-crystalline particles.

22. Claims 1, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Grebow et al. (US 5,618,845) and further in view of Hochlowski et al. (US 5,589,485).

23. Nguyen in view of Grebow have been described above to render over the liquid composition of claims 1 and 15. However, the composition of Nguyen in view of Grebow does not contain a further solvent or diluent according to claim 16. But, it is known that liquid formulations contain commonly used inert diluents such as benzyl alcohol, oils, propylene glycol

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and polyethylene glycols in addition to the active agent according to Hochlowski (see column 5, lines 35-43). Therefore, taking the teachings of the prior art references, one having ordinary skill in the art at the time the invention was made would reasonably expect that adding inert diluent such as benzyl alcohol or oils or propylene glycol to the composition of Nguyen as modified by the teaching of Grebow may further stabilize the liquid formulation as a preservative.

### ***Response to Arguments***

24. Applicant's arguments filed 11/25/08 have been fully considered but they are not persuasive.

25. Applicant argues that the combination of Nguyen, Grebow and Hochlowski does not teach all the elements of the claims since Nguyen in view of Grebow does not render claim 1 obvious. The examiner disagrees because Nguyen in view of Grebow has been shown above to render claim 1 obvious. Claim 16 depends on claim 15, which in turn depends on claim 1. Hochlowski is relied upon to show the further presence of solvents such as benzyl alcohol as recited in claim 16 and not to support the rejection of claim 1.

No claim is allowed.

26. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/  
Examiner, Art Unit 1618